510(k) Summary
for the APEX Spine System Line Extension

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the APEX Spine System Line Extension.

Date Prepared: August 13, 2013

1. **Submitter:**
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Westmont, IL 60559 USA
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Contact Person:
Ami Akallal-Asaad
Director of Regulatory Affairs.
SpineCraft, LLC
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2. **Trade name:** APEX Spine System Line Extension
Common Name: Spinal Fixation System
Classification Name: Pedicle screw spinal system per MNI 888.3070
Pedicle screw spinal system per MNH 888.3070
Pedicle screw spinal system per NKB 888.3070
Spinal interlaminal fixation orthosis per KWP 888.3050
Spinal intervertebral body fixation orthosis per KWQ 888.3060
Class III

3. **Predicate or legally marketed devices which are substantially equivalent:**

- APEX Spine System (K062513 / K092825 / K102488 / K110906) SpineCraft
- Viper Spine System (K090648 / K102701) DePuy
- Xia Spinal System (K113666 / K071373 / K060748) Stryker
- Tiger Spine System (K120969) CoreLink Surgical
- Firebird Spinal Fixation System, (K122901) Orthofix, Inc.
- REVERE® Stabilization System, (K093294) Globus Medical Inc

4. **Description of the device:**

The purpose of this submission is to add x-large and uniplanar pedicle screws, open iliac connectors and open-closed side-by-side connectors to the APEX Spine System. The APEX Spine System X-Large Screws are similar to the APEX screws and are available in a variety of diameters and lengths and can be used of the components of the previously cleared APEX Spine System. The APEX Uniplanar Pedicle Screw is similar in principle to the APEX Polyaxial Pedicle Screw; however the design restricts motion to the sagittal plane. The Open Iliac Connectors and Open-Closed Side-by-Side Connectors are utilized when pedicle screws are not vertically aligned.

Materials:
Titanium alloy per ASTM F136
CoCrMo alloy per ASTM F1537

5. **Substantial equivalence claimed to predicate devices**

APEX Spine System Line Extension is substantially equivalent to the APEX Spine System (K062513 / K092825 / K102488), Viper Spine System (K102701), Xia Spine System, Tiger Spine System (K120969), Firebird Spinal Fixation System (K122901), and REVERE® Stabilization System (K093294) in terms of intended use, design, materials used, mechanical safety and performances.

6. **Intended Use:**

The APEX Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

The APEX Spine System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 to S1), and for whom the device is intended to be removed after solid fusion is attained.

The APEX Spine System is also a sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous posterior approach with AIM MIS instrumentation, the APEX Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

7. **Non-clinical Test Summary:**

The following tests were conducted:

- ASTM F1717, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model". Testing included Static Compression Bending Tests, Static Torsion Tests and Dynamic Compression Bending Tests.
- ASTM F1798 "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies used in Spinal Arthrodesis Implants". Testing included Static Axial Gripping, Static Axial Torque and Dynamic Flexion-Extension.

The results of this testing were compared to predicate systems, with the results being equal or higher than the predicate systems.

8. **Clinical Test Summary**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical**

The APEX Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, performance and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

SpineCraft, LLC
Ms. Ami Akallal-Asaad
Director of Regulatory Affairs
777 Oakmont Lane
Westmont, Illinois 60559

Re: K132603
Trade/Device Name: APEX Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: September 9, 2013
Received: September 16, 2013

Dear Ms. Akallal-Asaad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indication for Use Statement

510(k) Number (if known): K132603

Device Name: APEX Spine System

Indication for Use:

The APEX Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132603